IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Babak NEMATI	Art Unit: 3763
Serial No.: 09/777,640	Examiner: M. Hayes
Filed: 7 February 2001	Atty. Docket: P66960US2
For: METHOD AND APPARATUS TO ENHANCE OPTICAL TRANSPARENCY OF BIOLOGICAL TISSUES	

DECLARATION OF BABAK NEMATI UNDER 37 C.F.R. 1.132

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In support of the accompanying response to the May 14, 2003 Office Action in the above-referenced matter, I hereby declare as follows:

1. My name is Babak Nemati. I am the inventor of the presently claimed invention. In 1990 I received a Bachelor of Science and a Bachelor of Arts degree in Mathematics and Physics, respectively; in 1991 I received a Master of Science degree in Electrical Engineering (emphasis in Applied Optics); and in 1995 I received a Ph.D. in Electrical Engineering (emphasizing Applied Optics), all from the University of Texas at Austin. Currently, I am the founder and president of Strategic Intelligence, a healthcare technology management consulting firm, and have served on boards associated with Optiscan Pty. Ltd., Plebys International, LLC, and the Lawrence Livermore National Laboratory. As further detailed in my *curriculum vitae*, attached hereto as Exhibit A, which is incorporated herein by reference, I have held management and executive positions with companies focused on healthcare, medical devices, and drug delivery.

2. I have firsthand experience in delivering agents to tissues in manners that minimize tissue damage. I also have firsthand experience with methods and compositions required for tissue optics, including enhancing transparency of tissues. My knowledge base further includes expertise with lasers, physics, drug delivery devices and the needs and limitations thereof, gained from work in academic, business, and medical forums.

3. I have reviewed the Office Action dated May 14, 2003, in the above matter and have considered the statements by the Examiner alleging that claims 37-56, 62, and 69 lack novelty under 35 U.S.C. § 102(b) as anticipated by Martinez (US 4,222,375). Although the Martinez apparatus is designed to illuminate internal tissue

before and during a medical procedure, the Examiner asserts the Martinez device comprises all elements, and is capable of performing all functions, of the presently claimed apparatus.

4. The presently claimed invention includes a means for bypassing a tissue permeability barrier with minimal tissue damage. The Examiner asserts that the needle disclosed by Martinez to deliver or receive fluid from tissue in the Martinez element can be used to bypasses the tissue permeability barrier. In my opinion, Martinez has no disclosure or suggestion that the needle, or any other element of the Martinez apparatus, is capable of bypassing a tissue permeability barrier, such as stratum corneum or conjunctiva of the eye, with minimal tissue damage. Even if the Martinez blunt needle was used to force through the surface permeability barrier, and thereby bypass it, it is my opinion that such use would result in more than minimal tissue damage, and would significantly compromise the anatomical integrity of the target tissue. Thus, it is my opinion that Martinez does not disclose a means to bypass the surface permeability barrier with minimal tissue damage.

5. It is additionally my opinion that the Martinez apparatus cannot be used to accomplish the same task as the presently claimed apparatus, as the Martinez apparatus cannot bypass the surface permeability barrier with minimal tissue damage.

6. I also have considered the statements made by the Examiner in the present Office Action in which claims 37-52, 54-56, 62-64, 66, and 69 were said to be obvious under 35 U.S.C. § 103(a) in view of Chan (US 6,275,726). In particular, the Examiner asserts that is well within the knowledge of the skilled artisan to make that which comprises plural parts into one part to simplify use of a device. The mere combining of the apparatus without a more specific recitation of the structural relationship between the parts is alleged to be obvious to one of ordinary skill in the art. I have reviewed the cited art and respectfully disagree with the Examiner's stated position.

7. With respect to Chan, it is my view that the "art" in question is the art of enhancing tissue transparency. In my experience, one of ordinary skill in this art is primarily concerned with methods and compositions for achieving tissue transparency. Once those problems are solved, a suitable light source is obtained and used, if needed. Accordingly, it is my opinion that, when I made my invention, one of ordinary skill in this art would not have had the requisite knowledge to conceive of an apparatus that combines (a) a means for bypassing a surface permeability membrane with minimal tissue damage, (b) a means for delivering a clarifying agent to the surface permeability membrane, and (c) a light source for light delivery to, or detection from, the target tissue. It was my expertise in all three areas that provided unique insight into the desirability of an apparatus that combined all three elements into one device. Thus, it is my view that it would not have been obvious to one of ordinary skill in the art to combine the separate elements disclosed by Chan into a single apparatus as presently claimed.

8. Moreover, in my opinion, it is not a trivial matter to combine into a single device the operational association of elements stated in the present claims. Thus, I do not

believe it would have been obvious to one of ordinary skill in the tissue transparency art that the porative means and delivery means can be operated simultaneously or sequentially, with the light means operated thereafter. The sequence of poration, delivery of clarifying agents (or simultaneous operation of poration and delivery of clarifying agent), followed by light delivery, can have a significant impact on the desired outcome of the tissue transparency process, as the perfusion of the clarifying agent in the interstitial space within the target tissue is a time dependent process. If the processes of poration, delivery of clarifying agent, and light delivery are activated out of an appropriate sequence, then the desired change in the optical properties of tissue are unlikely to be achieved.

9. Accordingly, it is my opinion that one of ordinary skill in the relevant art would not have the requisite insight or knowledge to combine the separate elements of Chan into a single apparatus.

10. I hereby declare that all statements made herein of my own knowledge and that all statements made on information and belief are true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

BABAK NEMATI, Ph.D.

Dated: September 10, 2003

EXHIBIT A TO
DECLARATION IN SUPPORT OF APPLICANT'S RESPONSE

Babak Nemati

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PROFESSIONAL EXPERIENCE

STRATEGIC INTELLIGENCE — San Diego, CA

Market-focused healthcare technology management consulting firm engaged in strategic planning, corporate development, clinical and regulatory, and product development and manufacturing consulting services

1/02 – Date ***Founder and President***

Established and conducted all aspects of SI's consulting practice. Exemplary list of consulting services include technology assessment, corporate partnering, strategic and tactical planning for commercial launch of medical device and drug-device combination products, venture development and financing services for start-up healthcare companies, and development of sales and marketing infrastructure for effective commercial launch in the US and European markets.

GENETRONICS, INC. — San Diego, CA

AMEX traded public company developing innovative therapeutic systems, based on electroporation-mediated drug and gene delivery, for applications in oncology, dermatology, cardiology, and gene therapy.

2/01 – 1/02 ***Executive Vice-President***

Directly managed corporate development and oncology marketing and sales activities of the Company, and indirectly provided strategic direction to Clinical, Regulatory, Research and Development, Engineering and Manufacturing Departments. Led all aspects of product launch efforts for the Company's proprietary surgical oncology platform technology in Europe. Secured sales and marketing infrastructure, including contract sales organizations, product distribution, servicing and support, and advertising agents across the European Union. Held expert panel meetings with surgical oncology thought leaders in Europe for market seeding of oncology products. Led financial road-shows across Europe, with interim CEO, to secure several rounds of equity financing. In the U.S. market, helped develop regulatory strategy and materially contributed to the design of the Phase III pivotal clinical protocol for treatment of head and neck cancers, that was submitted and approved by the U.S. FDA. Developed comprehensive strategic plan for partnering of Genetronics' proprietary drug-device combination products with major players in key healthcare sectors, including big pharma, specialty pharma, drug delivery companies, and major medical device companies.

8/00 – 2/01 ***Vice-President, Corporate Development.***

Led all business development and strategic planning activities of Genetronics. Defined and developed business plans for four key therapeutic fields within the Company, namely, oncology, gene delivery, dermatology and cardiovascular therapies. Identified key target companies in each therapeutic sector and forged relationships with market leaders in each field. Negotiated and closed collaborative research and licensing agreements in gene therapy with U.S. Navy, Chiron Corporation, Johnson and Johnson Research, Boeringher Ingelheim, and Valentis.

JOHNSON & JOHNSON

World's largest and most diversified healthcare company, with products in the pharmaceutical, consumer and professional market sectors, with aggregate sales of $30 billion annually.

9/99 – 8/00 ***Director, Surgical Oncology,*** **Ethicon Endo-Surgery, Inc.** Cincinnati, OH

Led the integration of an innovative drug-device combination product for localized treatment of solid tumors into the global development and commercialization processes of Ethicon Endo-Surgery. Instrumental in business planning and developing a global strategy for the growth of the newly formed oncology franchise. Devised strategies for new technology platforms to broaden product portfolio and led teams of scientists in evaluating the technical viability and market potential for new device and drug-device technologies in a broad range of oncology applications. Held expert panel meetings with thought leaders in oncology to validate clinical and regulatory strategies. Led the development of intellectual property strategy, research and development strategy, and contributed to the professional education curriculum development. Led due diligence around product and resource acquisitions.

10/98-9/99 ***Program Director, Oncology Products,*** **Ethicon, Inc.** Somerville, NJ

Global Project Leader for Ethicon's licensed electroporation platform technology for a wide range of indications in oncology. Led global clinical, regulatory, research and development, engineering design and manufacturing activities for the electroporation technology, and served a principal role in developing the strategic plan for Ethicon's global oncology franchise. Served as the key technical contact across Johnson and Johnson on the electroporation technology and established partnerships with other operating companies for pursuing the use of electroporation for gene delivery, transcutaneous drug delivery, and other non-oncology applications. Led all due diligence activities pertaining to licensing and acquisition of product opportunities in the field of surgical oncology. Served as the lead relationship manager in all interactions with our licensing partner, Genetronics. Led integration activities in transitioning the Genetronics development effort into Ethicon's global new product life cycle process. Received the *Silver Award* for leading the electroporation due diligence effort.

6/98 – 8/00 ***Chair, Global Council of Research Directors' Medical Optics Subcommittee*** New Brunswick, NJ

Founded Johnson & Johnson's first dedicated committee focused on coordination of the Corporation's activities in medical optics and leveraging the expertise and resources available across the J&J operating companies in this field. Developed a forum for technical and business exchange in Medical Optics, across the 180 Operating Companies. Organized targeted symposia for highlighting key emerging technologies of strategic interest to Johnson & Johnson. Provided recommendations for the Corporation on the merits and strategic value of key platform technologies in Medical Optics.

10/97-10/98 ***Manager, New Business Development,*** **Ethicon, Inc.** Somerville, NJ

Led identification, assessment, and licensing of new global opportunities, across a broad range of medical specialties, ranging from otolaryngology and dermatology, to surgical oncology, and assessed the strategic fit of these opportunities with Ethicon's overall growth strategy. Performed thorough business, clinical and technical assessment of new opportunities, and managed relationships with key internal and external business partners, as Ethicon's "lead contact". Served as an integral member of cross-functional teams focused on formulating strategy around new product opportunities. Presented new strategic opportunities to Ethicon's, as well as Johnson & Johnson's, corporate leadership. Led the entire due diligence process for Ethicon's licensed electroporation technology, which served as a cornerstone platform technology for Ethicon's entry into the field of surgical oncology. Received the *Silver Award* for outstanding contributions to Ethicon's global strategic planning.

5/96-10/97 **CANDELA CORPORATION** Wayland, Massachusetts

Leading manufacturer and worldwide distributor of laser dermatology and urology products (Nasdaq: CLZR).

Senior Manager, New Product Development.

Evaluated the technical and commercial viability of new product concepts, ranging from optical diagnostic systems to laser treatment modalities for dermatology and ophthalmic practices. Managed Candela's off-site clinical and pre-clinical research and development projects, and performed theoretical analysis of the underlying laser-tissue interaction mechanisms for new laser treatment modalities. Principal investigator for three SBIR projects, which received $1 million in funding from the National Institutes of Health. Managed the design, development, manufacturing, and marketing of Candela's Dynamic Cooling Device, which revolutionized laser treatment of pigmented and vascular lesions, and has since become an integral part of all laser hardware sold by Candela.

6/95-5/96 **SOMA RESEARCH CORPORATION** Austin, Texas

Comprehensive biomedical consulting firm specializing in technology development and commercialization, and market research.

Director, Technology Commercialization.

Managed Soma's consulting services for new and emerging technologies within the medical device industry. Carried out strategic technology search and identification, technology assessment, market research, product field evaluation, contract research and development, and management of pre-clinical and clinical investigations for medical device clients. Directly involved in new business development, strategic planning and administration.

3/93-4/95 **COHERENT MEDICAL, INC.** Palo Alto, California

World's leading manufacturer and distributor of medical laser products.

Consulting Project Leader.

Principal investigator for the development of the first clinically effective approach for transscleral argon cyclophotocoagulation, a laser treatment of end-stage glaucoma. Led all basic science research, pre-clinical research, and product prototyping activities.

3/92-3/93 **JOHNSON AND JOHNSON MEDICAL, INC.** Arlington, Texas

Consulting Investigator.

Co-principal investigator for the development of a *disposable* diode laser treatment system for general surgery applications. Conducted all basic science and pre-clinical research activities. Instrumental in securing intellectual property protection around research findings.

12/93-4/95 **NASA TECHNOLOGY COMMERCIALIZATION CENTER** Austin, Texas

Technology Assessment Associate.

Evaluated a wide range of technologies developed at Johnson Space Center and Ames Research Laboratory, and explored their market potential for a variety of medical applications. Assessed and developed a framework for commercialization of over 20 of NASA's most high-profile life science projects, including the NASA/Baylor axial-flow left ventricular assist device, a transcatheter system for ablation of arrhythmogenic cardiac tissues, and virtual reality systems for the rehabilitation of head injury patients.

EDUCATION

THE UNIVERSITY OF TEXAS AT AUSTIN

May 1995 **DOCTOR OF PHILOSOPHY** in Electrical Engineering (Applied Optics)
Minor in Biomedical Engineering

Dec. 1991 **MASTER OF SCIENCE** in Electrical Engineering (Applied Optics)
Minor in Biomedical Engineering

May 1990 **BACHELOR OF ARTS** in Physics *(With Special Honors)*
Minor in Electrical Engineering

May 1990 **BACHELOR OF SCIENCE** in Mathematics
Minor in Computer Science

BOARD MEMBERSHIPS

OPTISCAN PTY LTD

Publicly traded (ASX) world leader in in-vivo confocal microscopy, developed for applications in diagnostic imaging and scientific research

5/02 – 2/03 ***Advisory Board Member***

Assumed sole responsibility for the development of a comprehensive strategic and tactical plan for the U.S. launch of Optiscan's innovative diagnostic imaging platform, for applications in clinical and aesthetic dermatology, through diligent interactions with members of the Optiscan's executive management. Secured new alliances and sales and marketing infrastructure for Optiscan's entry into the U.S. marketplace.

PLEBYS INTERNATIONAL, LLC

Privately held company focused on creation, development, and growth of significant technology-based enterprises that meet underserved critical healthcare needs in global emerging markets.

3/01 – 3/03 ***Advisory Board Member***

Contributed to the development of a business plan for the newfound company for initial rounds of financing. Helped develop Plebys' strategic plan, positioning the company as a leader in the development and worldwide distribution of revolutionary healthcare technologies that meet significant unmet needs and that are beyond the reach of conventional corporate marketing and distribution efforts of multi-national corporations.

LAWRENCE LIVERMORE NATIONAL LABORATORY

U.S. Department of Energy national laboratory focused on applying science and technology in the national interest, with a focus on global security, global ecology, and bioscience.

10/96 – 1/00 ***External Advisory Board, Medical Technology Program.***

Reviewed overall strategic business plan with regards to Lawrence Livermore National Lab's technology transfer and technology development efforts in the life sciences. Instrumental in developing a strategic plan for achieving the Lab's commercialization objectives.